

Instructional Requirements for Investigators and Co-Investigators Affiliated with or Conducting Research within the Jurisdiction of Washington State Government Agencies

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Why is training important and necessary?

The primary responsibility for protecting human research subjects lies with researchers, their institutions, and institutional review boards. However, an exemplary system of protection requires more than compliance with existing policies and regulations. It requires conducting research “within a culture of concern and respect for research participants.”¹

Education and training in research ethics is central to fostering this culture of respect. In October 2000, NIH began to require documentation of completion of appropriate education in the protection of human research participants for all key personnel of research involving human subjects. In December 2000, as part of the new Federalwide Assurance (FWA) process, the federal Office for Human Research Protections (OHRP) initially required (and then later “strongly recommended”) all institutions conducting research under an FWA to establish “continuing programs to educate IRB members, IRB staff, and research investigators about human subject protection requirements.”²

The Washington State Government Agency training requirements are grounded in these federal requirements and reflect our belief that appropriate education and training is an important component of an effective system of human subject protections.

Who is required to take the human subject protection training?

Principal investigators and co-investigators of all research projects conducted in the jurisdiction of three Washington State Government Agencies (Department of Social and Health Services, Department of Health, and Department of Labor and Industries) are required to complete training in the protection of human research subjects. All research staff responsible for the design of the study, and all those in contact with human subjects and/or identifiable data (e.g., interviewers and data analysts), are strongly encouraged to take the training. Staff and members of the Washington State Institutional Review Board (WSIRB), the designated Institutional Review Board for these Washington State Government Agencies, are required to take the training.

¹ “Ethical and Policy Issues in Research Involving Human Participants, SUMMARY,” National Bioethics Advisory Commission, Bethesda, Maryland, August, 2001.

² See the FWAs for DSHS, DOH and L&I at (<http://www1.dshs.wa.gov/rda/hrrs/>).

What is the human subject protection training requirement?

Effective July 1, 2002, all principal investigators and co-investigators of new research proposals must have completed training in the protection of human research subjects within the past three years before their research will be approved by the WSIRB. Principal investigators and co-investigators of ongoing research projects must have completed a training course within the past three years before continuation approval for their research will be extended. Staff and members of WSIRB must complete training within three months of their employment or their initial appointment to the WSIRB, and must complete retraining every three years.

How can the training requirement be satisfied?

The training requirement can be satisfied by attending one of the in-person tutorials sponsored by the University of Washington or the Fred Hutchinson Cancer Research Center, or by completing an official training course sponsored by the researcher's home institution. Researchers should submit documentation of completion of this training when they submit their research proposal to the WSIRB.

Washington State Government Agency investigators and IRB members may satisfy the training requirement by completing the web-based course developed by the Collaborative IRB Training Initiative (CITI) and the University of Miami. Researchers whose home institution does not have an official training course may satisfy the training requirement by registering for the CITI course available on our website.

What is the CITI training course?

The **CITI Basic Course in The Protection of Human Research Subjects** consists of two tracks: one for **Biomedical Researchers (Group 1)** and one for **Social/Behavioral Researchers (Group 2)**. Each track includes modules that focus on different aspects of research ethics and human subject protection. Each module includes a brief quiz which must be taken to complete the module. While modules from either or both basic tracks may be taken, all required modules from one track must be completed to receive credit for the course.

Which CITI track should I take?

Researchers should select the track that corresponds to the type of research they typically conduct. All **Required Modules** in the selected track should be completed, as well as all **Optional Modules** that address topics related to the research submitted for review by the Washington State IRB.

How can the requirement for continuing education be satisfied?

CITI offers a **Refresher Course** that satisfies requirement for continuing education in the protection of human research subjects at least every three years. Researchers should take the **Refresher Course** only if they previously completed the **CITI Basic Course**. Researchers also may take the **CITI Refresher Course** if they previously completed an in-person tutorial sponsored by the University of Washington or the Fred Hutchinson Cancer Research Center, or if they previously completed an official training course sponsored by their home institution.

How long will it take to complete the CITI training?

The **CITI Basic Course** may take about 4 to 5 hours to complete. The **CITI Refresher Course**, which satisfies requirements for continuing education, takes about 1.5 hours to complete. Both courses may be broken into several sessions each devoted to completing one or more module and the related quiz.

How do I document that I have completed the CITI training?

When researchers complete all of the necessary modules they should submit their completion report to the WSIRB training coordinator. When all the necessary modules have been completed, the researcher's name will be posted on the [Washington State Agency List of Training Participants](#).

Who do I contact if I have questions?

Please contact Lilly Moneer, Training Coordinator, at 360 902-8075 or by email at wsirb@dshs.wa.gov.